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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,858	08/25/2000	Michael Dittgen	388A	5905

7590 09/10/2002

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/10/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,858

Applicant(s)

DITTGEN ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the first office action of September 13, 2001 and amendment, submitted March 12, 2002 is acknowledged. The amendment to claim 1 has overcome the objection the previous office action.

Claims 1-7 are herein examined on the merits.

This application contains claims 8-14 drawn to an invention nonelected without traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embase Abstract -272 in view of WPIDS abstracts -924 and -225, all references of record in parent application 08/738314, now USPN 6,133,251.

The Embase Abstract -272 teaches that triphasic estrogen/gestagen contraceptives are known in the art, see abstract. The claims differ primarily in that they are drawn to compositions and methods employing an estrogen, an estrogen in combination with a gestagen, an estrogen, and a placebo sequentially for specified periods of time. The WPIDS abstracts -924 teaches that the employment of estrogens (which may be natural) sequentially with a estrogen/gestagen combination in contraceptives is known.

One of ordinary skill in the art would have been motivated to employ the estrogen and estrogen/gestagen combination preparations of the WPIDS abstracts -924 in a triphasic method and/or preparation varying the dose of estrogen administered at different times in the cycle, since the benefits of varying estrogen doses in this way were known in the art. Triphasic estrogen/gestagen preparations were known broadly in the art to be useful means of contraception, see WPIDS abstract -225. Note also that the employment of medroxyprogesterone as the gestagen component of a contraceptive regimen is well known, see WPIDS abstract -225. Variations or optimizations of the dosage regimen of compounds well known to be administered together sequentially and in combination, are considered within the skill of the artisan.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-7 of U.S. Patent No. 6,133,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because Variations or optimizations of the dosage regimen of compounds well known to be administered together sequentially and in combination, are considered within the skill of the artisan.

Response to Arguments

Applicant's arguments filed March 12, 2002 have been fully considered but they are not persuasive. The declaration submitted under 37 CFR 1.132, and applicant's arguments based thereon have been considered, but are not found persuasive to overcome the obviousness rejection. Note that the comparative data provided in the instant declaration compares *one specific regimen, one specific estrogen and one specific progestin* claimed herein. i.e., 3 days of 3 mg of estradiol valerate alone, 4 days of a combination of 2 mg of estradiol valerate and 1 mg of dienogest, 16 days of a combination of 2 mg of estradiol valerate and 2 mg of dienogest, 2 days of 1 mg of estradiol valerate and three days of placebo. This showing is not commensurate in scope with the claims, thus the declaration is not persuasive to remove the obviousness rejection.

As to the obviousness double patenting rejection, applicant argues that "Claim 1 of the instant US patent application is broader. Applicants desire broader patent claim coverage and seek that broader coverage in the present application." Note that the Examiner is of the same

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opinion. The obviousness double patenting rejection herein is based on the fact that the scope of the claims of patent 6,133,251 and those of the instant application overlap, i.e., the claims in the instant application are broader than those in USPN 6,133,251 but nevertheless encompass the invention claimed in the issued patent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 26, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200